

PATENT APPLICATION

Filed: March 27, 2001

**RESPONSE UNDER 37 C.F.R. 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP NO. 1642**

Summary of the amendment

New claims 34-37 have been added to define specific embodiments of the invention. New claims 34-37 are directed at **confirming** the diagnosis of cancer in patients previously diagnosed as having cancer. Support for new claims 34-37 is found throughout the specification such as in paragraphs 0005, 0006, 0051, 0057, 0059-0061 of the published version of the specification, U.S. Patent Application Publication Number 20010039017. No new matter has been added.

Allowance of claims 25 and 27

Applicants acknowledge the indication of allowability of claims 25 and 27 in the Official Action and thank the examiner for the helpful comments provided therein.

Rejection of claims 29 and 31

Claims 29 and 31 stand rejected under 35 U.S.C 112, first paragraph, as containing subject matter not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is asserted that methods of diagnosing esophageal cancer using CDX2 are not enabled because they require undue experimentation. The reason given in support of the rejection is that "neither the instant specification nor the current state of the art provide any evidence that the assertion at page 11, lines 13-18 which says that CDX2 is expressed in esophageal cancer cells but not in normal esophageal cell is true or not." Applicants respectfully remind the examiner that it is well settled that the burden is on the Patent Office to establish by evidence and reasoning why Applicants' invention is not enabled. In the absence of such evidence and reasoning, the PTO must accept Applicants' assertions that the invention is enabled as true. The Applicant is under no duty to provide evidence of enablement in the absence of such evidence and reasoning in support of the rejection. No evidence or reasoning has been provided by the examiner to support the enablement rejection. The rejection is therefore improper and should be withdrawn.

Docket No.: TJU-2389

Serial No.: 09/819,252

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In an effort to facilitate prosecution and advance the application to allowance, Applicants provide herewith the Declaration under 37 CFR 1.132 of Dr. Scott Waldman, co-inventor of the claimed subject matter. Dr. Waldman's declaration contains data demonstrating that normal esophagus does not express CDX2 while esophageal cancer cells do. Dr. Waldman's declaration also contains (the abstract from) a recent scientific journal article which refers to data that indicate that normal esophagus does not express CDX2. The Declaration submitted with this Reply is unexecuted. A copy of the Declaration executed by Dr. Waldman will be submitted to the Patent Office in due course.

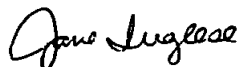
Applicants respectfully request that the rejection of claims 29 and 31 under 35 U.S.C 112, first paragraph, be withdrawn.

Conclusion

For the foregoing reasons, Applicants respectfully request that in addition to claims 25 and 27, claims 29, 31 and 34-37 are in condition for allowance. A notice of allowance is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Respectfully submitted,



Date: April 4, 2003

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Attachment: Declaration of Dr. Scott A. Waldman under 37 C.F.R. 1.132

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please add new claims 34-37 as follows:

New claim 34. A method of confirming the diagnosis of stomach cancer in an individual who has been diagnosed as having stomach cancer comprising the step of: examining a sample of stomach tissue from an individual who has been diagnosed as having stomach cancer to detect the presence of CDX2 transcript or translation product wherein the presence of CDX2 transcript or translation product in a stomach sample confirms the diagnosis of stomach cancer.

New claim 35. The method of claim 26 wherein the presence of CDX2 gene transcription product is determined by polymerase chain reaction wherein said sample is contacted with primers that selectively amplify CDX2 gene transcript or cDNA generated therefrom.

New claim 36. A method of confirming the diagnosis of esophageal cancer in an individual who has been diagnosed as having esophageal cancer comprising the step of examining a sample of esophagus tissue from an individual who has been diagnosed as having esophageal cancer to detect the presence of CDX2 transcript or translation product wherein the presence of CDX2 transcript or translation product in an esophageal sample confirms the diagnosis of esophageal cancer.

New claim 37. The method of claim 30 wherein the presence of CDX2 gene transcription product is determined by polymerase chain reaction wherein said sample is contacted with primers that selectively amplify CDX2 gene transcript or cDNA generated therefrom.